TELECONFERENCE OF THE BOARD OF SCIENTIFIC COUNSELORS, OFFICE OF INFECTIOUS DISEASES

Centers for Disease Control and Prevention

January 23, 2017
11:00 AM – 1:00 PM (EST)

A 2-hour open public teleconference of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), Centers for Disease Control and Prevention (CDC), was held on January 23, 2017. In addition to Board members and CDC staff, the meeting was attended by representatives of several public health partner organizations (Appendix).

The teleconference included an update from the BSC/OID Food Safety Modernization Act Surveillance Working Group (FSMA SWG); feedback from the December 2016 external review of CDC's Advanced Molecular Detection (AMD) program; and an overview of the 21st Century Cures Act. During the discussion that followed the FSMA SWG update, the BSC approved the annual FSMA report for forwarding to the Secretary, U.S. Department of Health and Human Services (HHS).

Opening Remarks

BSC/OID Chair Ruth Berkelman, Rollins Professor, Emory University, called the meeting to order and was joined in welcoming participants and facilitating introductions by Rima Khabbaz, CDC Deputy Director for Infectious Diseases, and Director, OID, and Robin Moseley, the BSC/OID Designated Federal Official. During roll call, BSC members noted no conflicts of interest.

Dr. Berkelman expressed her appreciation for Tom Frieden, outgoing CDC Director, and for Beth Bell, former Director of the National Center for Emerging and Zoonotic infectious Diseases (NCEZID). She also commended Anne Schuchat, who is serving as Acting CDC Director, and Dr. Khabbaz, who is also serving as Acting NCEZID Director while continuing to lead OID. Sarah Wiley, OID Senior Advisor, is assisting Dr. Schuchat as the Acting CDC Chief of Staff.

Dr. Khabbaz welcomed Jeff Duchin, Health Officer for Public Health – Seattle & King County, Washington State, as a new BSC member.

Report of the Food Safety Modernization Act Surveillance Working Group

The FSMA SWG, established in 2011, is charged through FSMA with providing advice and recommendations to CDC and the U.S. Food and Drug Administration (FDA)—and through them to HHS—on criteria for the designation of Integrated Food Safety Centers of Excellence (CoEs; criteria submitted in 2012) and improvement of foodborne illness surveillance. The Working Group includes 21 members representing the BSC, CDC, the U.S. Department of Agriculture (USDA), FDA, academia, consumer groups, industry, and state and local health organizations.

December 2016 FSMA SWG Meeting

Harry Chen, Chair of the FSMA SWG, reported on the topics discussed at the FSMA SWG meeting held on December 5–6: the potential influence of culture-independent diagnostic tests (CIDTs) on foodborne disease detection and control; the Interagency Food Safety Analytics Collaboration (IFSAC); and the impact of genomic testing on foodborne disease outbreak investigation and response.

1. **CIDTs and their potential influence on foodborne illness detection and outbreak surveillance and response**
    - CIDTs can detect a specific antigen or genetic sequence of an organism and do not require isolation of a living organism
    - Use of CIDTs, including for enteric pathogens, is increasing. The number of *Campylobacter* cases diagnosed by CIDTs more than doubled between 2010 and 2015. In 2011, there were five antigen-based CIDTs on the market (three for *Campylobacter* and two for Shiga toxin). By 2016, there were three additional antigen-based CIDTs for Shiga toxin and five PCR-based "syndromic panels" that can detect a range of enteric pathogens. By 2016, several clinical laboratories and private laboratory networks had begun using their own PCR-based laboratory-developed tests for enteric pathogens.
    - Benefits of CIDTs include faster detection to identify cases and guide clinical care; discovery of illnesses that would otherwise have gone undiagnosed; increased case ascertainment due to increased testing; use of one test to detect multiple agents; and lower costs
    - Challenges of CIDTs include false positives that can lead to unnecessary treatment, unnecessary case follow-up, and investigation of pseudo-outbreaks; loss of antimicrobial resistance (AR) testing; decreased ability to detect dispersed outbreaks; decreased ability to monitor disease trends; and less specificity
    - Decreased use of culture-based tests is leading to reduced availability of bacterial foodborne isolates needed for
        - Serologic subtyping and subtyping by pulsed-field gel electrophoresis (PFGE)
        - Molecular subtyping by whole-genome sequencing (WGS) and multiple-locus variable-number tandem-repeat analysis
        - Culture-based tests to assess antimicrobial susceptibility
    - CDC has developed a three-step plan to meet this challenge:
        - Step 1: Preserve a sufficient number of cultures to allow continued use of current methods for surveillance of foodborne diseases. One strategy is to encourage reflex-testing (confirmatory culture-based testing performed when a sample tests positive by CIDTs) by clinical laboratories.
        - Step 2: Build a sequence-based infrastructure for disease surveillance. PulseNet, the national laboratory network for surveillance of foodborne illness, is transitioning from its current subtyping method (PFGE) to WGS (see also page 5).
        - Step 3: Implement metagenomic techniques for direct characterization of genomic sequences within clinical specimens. These techniques do not require isolates for diagnosis or subtyping.

Feedback from the FSMA SWG on CIDTs

How can monitoring of CIDT use be improved? The FSMA SWG suggested that CDC

- Continue to monitor the adoption of CIDTs and determine the percentage of positive results identified from CIDTs. This might be accomplished by
  - Conducting a national FoodNet laboratory survey
  - Including a variable on test methods in forms used to report cases of foodborne illnesses
  - Requiring recipients of CDC Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement awards to submit data on CIDT use
- Continue to be transparent about uncertainties in sensitivity and specificity of CIDT data and in calculating disease incidence and trends based on these findings
- Establish criteria for data quality by standardizing and validating diagnostic tests
- Help move towards development of a new consensus on a "gold standard" for enteric disease testing

How can cultures be maintained until unnecessary? Culture-based testing will continue to be needed to monitor the emergence of new and emerging threats and to detect new AR genes and patterns of resistance. The FSMA SWG recommended that CDC

- Support efforts by local health departments to
  - Collect patient samples during investigations of foodborne disease clusters detected by CIDTs
  - Fill gaps in surveillance for specific pathogens in specific regions of the country
- Encourage and facilitate reflex-testing by clinical laboratories
- Use sentinel surveillance networks (e.g., FoodNet) to monitor the impact of CIDT use for foodborne pathogens of local or regional public health concern

How should surveillance and investigations be modified for CIDT use? To assess the impact of disease reporting based on CIDTs on FoodNet estimates of disease incidence and disease trends, the FSMA SWG recommended that CDC

- Assess performance characteristics of CIDTs and determine whether false negatives and/or false positives are a significant issue
- Confirm clinical correlations between test results and illnesses, especially when more than one pathogen tests positive on a syndromic panel
- Determine whether physicians' ordering practices are changing and whether larger numbers of sporadic cases of disease are being detected as CIDTs replace culture-based tests
- Determine whether, how, and why use of CIDTs is changing among certain population subgroups and within certain states or geographic regions

2. Interagency Food Safety Analytics Collaboration

- IFSAC is a collaboration between CDC, FDA, and USDA's Food Safety and Inspection Service (FSIS) that works to generate estimates of foodborne illness source attribution and inform food safety policy

- The goals of the 2017–21 IFSAC strategic plan are to
  1. Improve the use and quality of new and existing data sources to conduct analyses and develop estimates of foodborne illness source attribution, focusing on four priority pathogens: *Salmonella* spp., *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter*
  2. Improve analytic methods and models
  3. Enhance the use of and communication about IFSAC products
- Ongoing IFSAC projects include
  - Creating a template for an annual IFSAC report, with updated attribution percentages by food category for the four priority pathogens
  - Assessing the attribution percentage of norovirus to illness associated with consumption of shellfish
  - Evaluating the potential use of foodborne disease datasets in identifying food contamination points and developing a predictive model to anticipate where contamination is most likely to occur
  - Improving attribution of *Campylobacter* transmitted by different routes
  - Developing methods for estimating attribution of disease to complex (multi-ingredient) foods
  - Evaluating temporal trends in food categories implicated in outbreaks involving the four priority pathogens
  - Updating estimates of the proportion of *Salmonella* Enteritidis illnesses attributable to eggs, chicken, and other foods

Feedback from the FSMA SWG on IFSAC

Are the focus and goals of IFSAC appropriate? The FSMA SWG approved the focus and goals of the IFSAC strategic plan. They suggested that IFSAC consider adding information on

- Communication with policy-makers and the public about food safety
- The role of industry and industry scientists
- The role of the CoEs
- The plan's priorities, in terms of pathogens (e.g., *Salmonella* as the first priority)
- A needs assessment strategy to identify data gaps, clarify data flows, and consider data sources and access and harmonization issues
- How attribution data inform food safety policies
- Building the U.S. food safety research workforce

Other activities suggested by the FSMA SWG included

- Using IFSAC attribution studies as opportunities to identify optimal ways to combine epidemiologic data with WGS data to address public health questions
- Aligning IFSAC research activities on foodborne AR with related research activities conducted in fulfillment of the *National Action Plan for Combating Antibiotic-Resistant Bacteria* (CARB)

Comments on IFSAC projects. The FSMA SWG made the following general suggestions:

- For each IFSAC project, include a statement explaining which IFSAC objective(s) the project addresses
- Make tools developed for IFSAC projects available to others (e.g., via the CoEs)
- Encourage harmonization of terminology and a culture of constant quality improvement (CQI)
- Work with academic institutions and graduate fellows to develop innovative tools and approaches
- Use graphics to share and display IFSAC data

The FSMA SWG also made suggestions related to specific IFSAC projects:

- *Evaluating points of contamination:* Consider separating out restaurant-associated food contamination and contamination associated with food-processing
- *Improving attribution of* Campylobacter*:* Assess the amount of *Campylobacter* transmission due to contaminated produce, which is likely to be large
- *Developing a predictive model for identifying points of contamination:* Consider collaborating with the risk assessment group at the FDA Center for Food Safety and Applied Nutrition (CFSAN)

3. Genomic testing (e.g., WGS) and its potential effects on foodborne outbreak investigations and response

- As discussed above, PulseNet is transitioning from use of PFGE to WGS. This change will
  - Provide greater specificity when matching clinical, environmental, and product isolates
  - Allow investigators to use fewer isolates in identifying linkages between illnesses and potential sources of contamination. Investigators can therefore be deployed in a more targeted manner, saving resources.
  - Facilitate faster identification of the food involved in an outbreak
  - Allow cost-efficient consolidation of multiple workflows, providing information on serotype, drug resistance, virulence, and other critical factors in a single assay, with the same technical approach used for all pathogens
- As part of the PulseNet transition to WGS,
  - Capacity for sequencing and data analysis will be established in all 50 states by the end of 2017, and PFGE will be gradually phased out, starting in 2018
  - Public health laboratories will analyze WGS data using whole-genome multilocus sequence-typing (wgMLST), using a wgMLST database validated and deployed by CDC. A second method, high-quality single nucleotide polymorphisms (hqSNP), may be used by FDA laboratories for confirmatory testing that may be needed to support regulatory action.
  - PulseNet laboratories and laboratories that participate in FDA's GenomeTrakr system will continue to upload WGS data to a National Institutes of Health (NIH) National Center for Biotechnology Information (NCBI) database in near real-time

- The benefits of WGS are illustrated by
  - The *Listeria* WGS Project, a collaboration among CDC, FDA, USDA, NCBI, and state and local health departments, which found that using WGS to monitor *Listeria* led to faster and better detection of disease clusters and more successful outbreak investigations
  - Use of WGS during a 2015–16 investigation of a multistate outbreak of *E.coli* O121 to link clinical isolates to isolates from contaminated flour and commercial products made from the contaminated flour

FDA perspective on WGS

- WGS is used on a routine basis in FDA's outbreak response, compliance, and disease surveillance activities
- WGS has been used successfully to trace foodborne contamination events
- FDA is using WGS for many non-regulatory purposes (e.g., to improve supply chain management, quality assurance, and process evaluation)
- FDA will need to balance the need for an increased number of well-characterized environmental sequences (e.g., from food, water, and facilities) with the need for an increased number of clinical isolates

USDA FSIS perspective on WGS

- FSIS is building capacity to sequence all FSIS isolates (around 10,000 per year). FSIS currently operates six sequencers at its Eastern Laboratory and expects to achieve full capacity with 10 sequencers.
- When taking regulatory action, FSIS considers WGS data in combination with PFGE data, epidemiologic data, and microbiologic data
- FSIS participates in efforts by the Interagency Collaboration on Genomics and Food Safety (Gen-FS)—along with CDC, FDA, and NCBI—to harmonize standards and metrics for using WGS to improve food safety

Feedback from the FSMA SWG on WGS

How can coordination of WGS between agencies be improved? The FSMA SWG suggested that CDC, FDA, and FSIS

- Identify and address obstacles to collaboration and data-sharing
- Disseminate information about publicly accessible WGS databases
- Collaborate with industry and academia on use of WGS datasets
- Encourage collaboration between public health and agricultural sectors
- Engage other countries in global efforts to prevent foodborne disease

What resources are needed to implement and respond to WGS data? The increased use of CIDTs along with the transition from PulseNet to WGS are likely to result in the identification of more outbreaks of foodborne illnesses. The FSMA SWG suggested that CDC

- Estimate how many more outbreaks are likely to be detected and the resources that will be needed to investigate them

- Encourage local health departments to
  - Partner with local agricultural departments, FDA offices, and environmental health specialists
  - Document the costs of investigative activities
- Consider whether local health departments should prioritize investigations based on causative agent and cluster size

How can the effects of WGS be monitored better? The FSMA SWG suggested that CDC

- Apply the same metrics and mechanisms used in past years to monitor PulseNet. For example, CDC might use data collected by FoodNet and FoodCORE (Foodborne Diseases Centers for Outbreak Response Enhancement) to answer these questions:
  - Has the number of foodborne illnesses decreased?
  - Is the number of clusters higher while the number of illnesses per cluster is smaller?
  - Has WGS allowed detection of cases or clusters that would not have been detected with PFGE?
- Work with industry partners to develop new metrics to assess the impact of WGS testing on food industry practices and disease prevention efforts

FSMA SWG Topics for 2017

Suggested agenda items for the FSMA SWG in the coming year include

- Periodic reviews of components of the national foodborne surveillance system (e.g., FoodNet, NORS [National Outbreak Reporting System], and OutbreakNet)
- Integration of data systems among CDC, FDA, and USDA
- Updates on interagency collaborations (e.g., IFSAC, the Interagency Foodborne Outbreak Response Collaboration [IFORC], and Gen-FS)
- Food safety challenges associated with imported foods
- Orphan illnesses (e.g., toxoplasmosis, cryptosporidiosis, and hepatitis A)
- Measuring the impact of FSMA
- Assessing the PulseNet transition at the state and local levels, with special attention to workforce training

BSC Discussion

BSC members recommended that CDC and FDA

- Work with food scientists in industry and academia to improve CIDTs, which may have good sensitivity but poor specificity
- Convene a meeting on CIDTs to inform epidemiologists about CIDT issues and build partnerships to facilitate the public health transition from culture-based tests to CIDTs. Another approach would be to include a presentation and discussion of CIDTs at the next International Conference on Emerging Infectious Diseases (ICEID).

BSC comments about reflex-testing as a short-term solution to loss of bacterial isolates included the following:

- FDA should continue to work with industry partners to encourage reflex-testing (e.g., by providing instructions on reflex-testing in package inserts)
- The reflex-testing approach will not work because clinical laboratories have limited budgets and other constraints. CDC should take a different approach, such as establishing well-targeted sentinel surveillance projects. The Gonococcal Isolate Surveillance Project (GISP) is a good model.

Other comments from BSC members included the following:

- In some states, increased use of CIDTs has already led to detection of larger numbers of norovirus outbreaks. In the future, many local health departments will require additional epidemiologic resources to conduct a larger number of outbreak investigations. If those resources are not available, it may be necessary to prioritize investigations based on causative agent and outbreak size, as suggested by the FSMA SWG.
- Progress towards integration of WGS data by CDC, FDA, and USDA is excellent; harmonization of sequencing and analytic methods is also important to move things forward
- The FSMA SWG might serve as a model for other working groups that aim to strengthen infectious disease areas that need strengthening, such as vector control and waterborne diseases

FSMA SWG Annual Report to the HHS Secretary

The FY 2016 annual report was endorsed by the FSMA SWG, with one abstention (from a new member) and no dissents. The report addresses five key topics:

- Engaging industry
- Reviewing the Interagency Food Safety Analytics Collaboration
- Enhancing Foodborne Traceback Investigations
- Improving the Integrated Food Safety Centers of Excellence
- Expanding Foodborne Antimicrobial Resistance Surveillance

External Review of CDC's Advanced Molecular Detection Program

CDC's AMD program is a $30 million-per-year program established in 2014. Its aims are to

- Bring next-generation sequencing and bioinformatics into efforts against public health threats in the United States
- Facilitate the adoption of related technologies into public health

The AMD program is currently in the 4th year of its initial 5-year strategic plan and is starting to plan for Year 6 and beyond. Greg Armstrong, Director, Office of Advanced Molecular Detection (OAMD), NCEZID, presented feedback from an external review of CDC's AMD program, which was held on December 1–2, 2016. The objectives of the nine-member panel of experts were to review AMD progress in Years 1–3; propose adjustments to plans for Years 4–5; and review and comment on

tentative priorities for Year 6 and beyond. The panel issued individual recommendations in the following areas:

- **AMD leadership.** The external reviewers recommended that OAMD
  - Consider succession planning
  - Establish a more effective steering committee involving both CDC laboratory and epidemiologic leadership
  - Enlist outside expertise

  To address these recommendations, OAMD has asked that the Associate Directors for Laboratory Science from the Center for Global Health (CGH); NCEZID; the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP); and the National Center for Immunization and Respiratory Diseases (NCIRD) serve on the AMD Steering Committee, and will also invite the Associate Directors for Epidemiologic Science from these four centers to the Steering Committee meetings on a periodic basis. OAMD will also ask the BSC/OID Infectious Disease Laboratory Working Group (IDLWG) to provide ongoing guidance. To improve succession planning, CDC will consider options for expanding OAMD.

- **AMD priorities.** The external reviewers recommended that OAMD
  - Focus spending on projects with public health impact and those leveraging the unique strengths of CDC and state public health
  - Improve evaluation of programs
  - Develop a framework for defining "public health impact"

  To address these recommendations, OAMD will update the process by which AMD projects are selected and funded in Year 6 to improve their alignment with public health priorities. OAMD will also improve evaluation of AMD projects in terms of 1) operational impact (in collaboration with the CDC Health Economics Modeling Unit) and 2) epidemiologic impact (in collaboration with economists and evaluators within the infectious disease programs—this will take a longer period of time to execute). OAMD will also develop a "public health impact" framework under which to consider how to evaluate AMD innovations in terms of impact on disease burden and on cost-effectiveness.

- **Translation: public health impact.** The external reviewers noted that OAMD should work to better
  - Engage epidemiologists, now that AMD data are coming online
  - Integrate genomic and epidemiologic data
  - Obtain improved tools for analyzing and visualizing data
  - Coordinate AMD applications used by state health departments

  To address these recommendations, OAMD will provide training opportunities for epidemiologists at CDC and work with the Food Safety CoEs to provide training opportunities for epidemiologists at state and local health departments. OAMD will also support projects conducted by NCHHSTP and CDC's Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) to integrate genomic and epidemiologic data. Last year, OAMD issued a Broad Agency Announcement (BAA)[1] to obtain

[1] BAAs are used by U.S. Government agencies to solicit proposals from outside groups for certain types of research and development.

tools for data analysis and visualization, in collaboration with Imperial College, London; in 2017 OAMD and the CDC Office of the Associate Director for Science may participate in additional BAAs.

To help coordinate use of AMD applications by state health departments, OAMD will work with partners to harmonize laboratory methods for construction of genomic libraries for bacteria and viruses. OAMD is also considering three options for harmonizing methods for analysis of WGS data involving the use of 1) BioNumerics software, 2) a single AMD portal with DNA analysis tools, or 3) the cloud-based APHL (Association of Public Health Laboratories) AIMS Platform.

- **Workforce development.** The external reviewers recommended that OAMD
  - Promote collaboration with academia
  - Consider offering AMD training at APHL and Council of State and Territorial Epidemiologists (CSTE) annual meetings
  - Consider integrating AMD training into Epidemic Intelligence Service (EIS) and Laboratory Leadership Service (LLS) fellowships

  OAMD will continue its collaboration with the Georgia Institute of Technology and work with the CoEs and other academic partners to expand AMD training for epidemiologists. State and local health departments may also expand their training networks and partnerships with academic institutions, and the ELC program will pilot a program to provide bioinformatics resources on a regional basis. APHL and CSTE plan to provide training sessions at their annual meetings, and the EIS and LLS fellowships will include AMD trainings as part of their orientation courses.

- **Capacity in state and local health departments.** The external reviewers recommended that OAMD
  - Engage states early in each stage of the process and promote innovation at the state level
  - Consider developing a higher level of sequencing capacity in regional laboratories
  - Expand placement of Bioinformatics Fellows in state laboratories
  - Expand AMD Day

  To address these recommendations, OAMD will re-engage with the Emerging Infections Programs (EIPs), beginning with the EIP Steering Committee meeting in February. OAMD will also collaborate on a CARB-funded pilot program to establish higher-level sequencing technology (with a robotics station) in at least one regional laboratory. OAMD will encourage placement of Bioinformatics Fellows in state health departments (as it did last year), expand AMD Day to 2 days, and increase support for participation of state-level colleagues in AMD Day and ICEID.

In addition, the reviewers recommended that OAMD continue to assist the states with information technology (IT) issues; make more use of the cloud going forward; be selective in early adoption of new technologies; consider outsourcing some sequencing projects; and consider the need for additional bioinformatics experts with good communications ("translational") skills. The reviewers also noted that rapid expansion of next-generation sequencing and bioinformatics at CDC has increased the need to establish consistent quality control standards.

BSC Discussion

BSC members commended the progress made by OAMD and the leadership of Greg Armstrong and Duncan MacCannell, the Senior Advisor for Bioinformatics. Comments included the following:

- While putting AMD technology in place was the first step, the second is to integrate WGS data with epidemiologic data and improve public health practice at the state and local levels
- New analytic methods will be needed to
  - Detect antibiotic resistance that is due to unknown or newly generated mutations
  - Prepare for and take advantage of the coming "avalanche" of AMD data. Public health laboratories are making progress in this area, and epidemiologists must also find ways to make good use of large data sets. The National Academy of Medicine Forum on Antimicrobial Threats has established a subgroup on big data that includes representatives from public health, academia, and industry.
- An ongoing challenge is to further expand and leverage collaborations and consultations with academic and private sector partners who can help transfer AMD techniques to the states and provide guidance on software and analytic techniques. OAMD should also consider expanding partnerships with clinical laboratories.
- Partnerships with academic institutions can help graduate students and postdocs in laboratory and epidemiology programs better understand public health issues and develop creative solutions to address them
- Dr. Armstrong noted that the BAA process is interactive and can be a useful way to reach out to groups in academia and the private sector
- Beth Lautner, USDA, noted that FSIS and CDC can work together to use AMD techniques to address One Health issues related to zoonotic diseases, *Salmonella*, influenza, TB, and drug-resistant diseases

Overview of the 21st Century Cures Act

Karyn Richman, Acting Director, CDC Washington Office, and Miranda Katsoyannis, Senior Program Analyst, CDC Washington Office, provided a brief overview of the 21st Century Cures Act (signed into law on December 13, 2016) and highlighted provisions related to public health.

The 21st Century Cures Act includes support for the NIH Cancer Moonshot, BRAIN (Brain Research through Advancing Innovative Neurotechnologies®), and Precision Medicine initiatives and for faster drug review procedures by FDA. It also includes funding for the Substance Abuse and Mental Health Services Administration (SAMHSA) to increase opiate addiction treatment. Of special interest to CDC, the Cures Act expands the Paperwork Reduction Act waiver to apply to public health emergencies. It also amends travel rules to make it easier for high-level CDC staff to attend scientific conferences.

Other topics covered by the Cures Act include

- *Vaccines:* CDC will share vaccine data with the Advisory Committee on Immunization Practices (ACIP) and other stakeholders in a more formal way, and the CDC Director will review ACIP criteria for making recommendations, as well as ACIP processes for ensuring the consistency of processes in making recommendations. CDC will also work with the HHS National Vaccine Program Office to encourage vaccine innovation.

- *Monitoring antimicrobial resistance:* The Cures Act requires HHS to provide guidance and report to Congress about antibiotic stewardship and AR trends on an annual basis. HHS will also assist the states with AR prevention activities and develop a form for AR reporting at the state level.
- *Tick-borne diseases:* The HHS Secretary is charged with supporting clinical research on vector-borne diseases (including tick-borne diseases) to improve prevention, diagnosis, and treatment. HHS will establish a 6-year FACA (Federal Advisory Committee Act) working group on vector-borne diseases with federal (including CDC) and non-federal members.
- *Neurologic diseases:* The Cures Act authorizes $5 million per year for national surveillance for up to five neurologic diseases to be selected by HHS
- *Interoperability:* The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with other federal entities and stakeholders, is required to develop and publish on its website a trusted exchange framework and a common agreement among existing health information networks to exchange electronic health information, as steps in achieving an interoperable nationwide health information network. Additionally a new committee, the HIT (Health IT) Advisory Committee, will replace and assume responsibilities of existing committees, and is required to produce annual progress reports on advancing interoperability nationwide. CDC will be part of this new advisory committee.
- *Medical countermeasures:* The Cures Act provides support to the Biomedical Advanced Research and Development Authority (BARDA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) for applied research on countermeasures. It also supports the development of utilization guidelines for countermeasures stored in the Strategic National Stockpile.

A summary of the 21st Century Cures Act will be provided to BSC members by OID.

BSC Discussion

In response to questions about the 21st Century Cures Act, Ms. Richman explained that

- The 21st Century Cures Act does not include funding for infectious disease prevention, because prevention funds were (up until now) provided to CDC through the Prevention and Public Health Fund (PHHF) of the Affordable Care Act (ACA). Repeal of the ACA would eliminate those funds, which are 10% of CDC's budget and support childhood vaccination activities, ELC funding for the states, and prevention activities for non-communicable diseases. Approximately half of the PHHF monies support activities at state and local health departments. The CDC Washington Office is communicating the importance of these public health programs to partners and appropriators.
- The ACIP provisions in the 21st Century Cures Act about data-sharing and reporting incorporate input from CDC

In regard to a question about the AMD program and the Cures Act, BSC members recommended that

- AMD should adopt a systems biology approach to the integration of WGS data into public heath practice
- CDC should intensify efforts to develop metagenomic techniques. Dr. Armstrong noted that IDLWG has also recommended increased CDC investment in this area.

Phone Lines Open to Partners and the Public

Scott Becker, APHL, commended OAMD and AMD leaders and asked about engagement of public health laboratories in AMD activities. Dr. Armstrong responded that the laboratories have been enthusiastic partners and that the epidemiologists are now on board as well. The magnitude of WGS data—far greater than usually seen in public health studies—has raised many bioinformatics issues, and CDC is working with APHL to assist state laboratories with this new challenge. Mr. Becker noted that some states have been working on these issues for some time, while others are waiting on direction and assistance from CDC.

Adjournment

Dr. Berkelman thanked the participants and adjourned the meeting at 1:00 PM (EST).

BSC Member and CDC Staff Participants*

BSC Members

Ruth Berkelman	Emily Erbelding	Bonnie Maldonado
Jack Bennett	Dawn Fukuda	Beth Marlowe
Nancy Bennett	Bruce Gellin	Andy Pavia
Luciana Borio	Tim Jones	Susan Sharp
Kristy Bradley	Salmaan Keshavjee	Jill Taylor
Mike Brady	Beth Lautner	Judy Wasserheit
Harry Chen	Jim Le Duc	Deb Yokoe
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Greg Armstrong	Alexandra Levitt	Michele Owen
Kim Distel	Duncan MacCannell	Bob Pinner
Marta Gwinn	Nancy Messonnier	Karyn Richman
Miranda Katsoyannis	Dale Morse	Jim Seligman
Rima Khabbaz	Robin Moseley	Michael Shaw

*Callers also included individuals from OID partner organizations and members of the public.

I hereby certify that to the best of my knowledge, the foregoing minutes of the proceedings of the meeting of the Board of Scientific Counselors, Office of Infectious Diseases, on January 23, 2017, are accurate and complete.

/S/ 03/23/17

Ruth Berkelman, M.D. Date
Chair, BSC, OID